EXHIBIT G

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UGNJ
777 Bloomfield Avenue
Glen Ridge, NJ 07028
973-429-0462 (phone) • 973-748-1236 (fax)
www.montclairurology.com
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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**MDL No. 2327**
	2:12-md-02327
THIS DOCUMENT RELATES TO:	**HON. JOSEPH R. GOODWIN**
Joanne Phillips v. Ethicon, Inc., et al No. 2:12-cv-02489	

RULE 26 EXPERT REPORT OF KONSTANTIN WALMSLEY, MD

My name is Konstantin Walmsley. I have been retained by the Motley Rice Law Firm to give medical opinions related to Joanne Phillips. I am being compensated at the rate of $500 dollars/hour. My curriculum vitae and schedule of previous testimony are attached to this report. All opinions set forth in this report are based upon my personal knowledge, as well as my review of the pertinent medical records, my education, training, skill, experience as a physician, and review of the pertinent medical literature. All of my opinions are based upon a reasonable degree of medical probability.

I am a licensed physician in the State of New Jersey and a board certified urologist. I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh and am familiar with the properties of these devices and proper implantation technique for these devices.

I am familiar with the evaluation and treatment of stress urinary incontinence. I have implanted transvaginal mesh, including mid urethral slings, and am familiar with the properties of these devices and proper implantation technique for these

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devices. Further, I am familiar with non-mesh options for the treatment of stress urinary incontinence including the pubovaginal sling. I have attending training provided by Ethicon, Inc. regarding the TVT device. I have explanted and performed other revision procedures on transobturator and retropubic mid-urethral slings including the TVT device.

Additionally, in light of my training, knowledge, experience and qualifications as set forth above and in the attached C.V., I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants.

The most common complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion, exposure or protrusion of mesh into and through tissues or organs, voiding dysfunction relating to pelvic floor scarring (de novo urinary urgency, urge incontinence, and incomplete emptying), and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the cause of the patients complications based upon an interview with the patient, a review of her medical records, and knowledge of her prior medical history.

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Joanne Phillips:

- University of Tennessee Medical Center;
- University Urology, PC;
- Lafollette Health Clinic;
- Summit Medical Group of Oak Ridge;
- Lafollette Medical Center;
- Active Pain Treatment;
- Riggs Jacksboro Drug Store;
- Tennova General Surgery;
- Dr. Edward D. Kim;
- Deposition – Joanne Phillips
- Deposition – Edward D. Kim

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In addition to the review of the medical records listed above, I performed an independent medical examination of Joanne Phillips on June 17th, 2016. I have also reviewed medical literature and other TVM related documents and have relied, in part, on the documents enclosed in my reliance list provided as **Appendix A**.

Clinical History

- On October 25th, 2004, Ms. Phillips presented to Dr. Kim with complaints of urinary incontinence. Her past medical history was in part remarkable for a total abdominal hysterectomy performed 10 years ago, a history of persistent low and cervical back pain requiring significant pain medication, and 2 C-sections. Her subjective complaints were consistent with mixed urinary incontinence (MUI) with a primary stress urinary incontinence (SUI) component. Her symptoms had developed over the last 5 months, gradually worsening over this time period. She had some right-sided abdominal pain over the preceding 2 weeks and had an intravenous pyelogram (IVP) performed that was read as normal. She was prescribed Detrol LA and advised to return in one month.

- On November 24th, 2004, she returned to Dr. Kim's office noting improvements with regards to her overactive bladder (OAB) and urgency urinary incontinence (UUI) symptoms while on Detrol LA. She continued to have SUI but preferred active surveillance of this problem for the time being.

- On January 10th, 2005, because of persistent bothersome SUI symptoms, Ms. Phillips underwent a retropubic TVT sling insertion. The operation proceeded smoothly, and Dr. Kim placed the sling in a tension-free fashion, using Mayo scissors as a spacer between the urethra and the sling.

- On December 13th, 2005, Ms. Phillips presented with complaints of lower back pain and pain in the lower abdominal wall where she had a scar form her sling surgery.

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- Between February 2006 and June 2012, Ms. Phillips had multiple visits to the Lafollette Health Clinic mostly with issues related to back pain and uncontrolled diabetes. At some point in August of 2009, she was prescribed Premarin and advised as to its side effects.

- On September 10th, 2012, she presented to University Urology with a request to have her bladder sling removed, in part complaining of dysuria.

- On October 10th, 2012, she returned to University Urology with a 5 month complaint of vaginal cramping and occasional bleeding. She complained of frequency, leaking with coughing, hematuria, dysuria, and urgency, and nocturia more than 6 times. She refused a pelvic and was advised to consider a second opinion with another urologist.

- Between October of 2012 and April of 2014, Ms. Phillips had multiple visits to the Lafollette Health Clinic mostly with issues once again mostly related to back pain and uncontrolled diabetes. In October of 2013, having complaints of dysuria and some left flank pain, and she was diagnosed with a UTI.

Methodology

My general opinions are based upon my clinical experience and review of medical and scientific literature and well as my medical education, knowledge, training, practice, and clinical experience.

My case specific opinions are based upon a differential diagnosis methodology. In determining the specific cause of an injury in the medical context it is necessary to "rule in" potential causes of the injury, and then by process of climination, to "rule out" the least likely causes to arrive at the most likely cause.

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General Opinion No. 1

Facilitating informed consent is an integral part of the practice of medicine. I agree with AMA 8.08 on informed consent. The patient's right of self-decision is particularly important when surgical intervention regarding a permanent medical device is being considered by the patient.

Before a surgeon can inform a patient on the risks/benefits/alternatives to any procedure, including the TVT, the surgeon must be informed on the risks/benefits/alternatives. I have read and relied on Instructions for Use (IFU) for medical devices when informing myself on the risks/benefits/alternatives to a given procedures – including mid-urethral slings. I incorporate the risks and complications referenced in the IFU into my risk benefit conversation with the patient. I expect the risk and complication information as presented in the IFU to be accurate.

It is my opinion the IFU for the TVT in 2005 were not sufficient to enable informed consent from the patient. The TVT IFU provided:

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin fibrous layer of tissue which can grow through the interstices of the mesh,

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thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

The words "transitory" and "transient" carry a specific medical meaning. Mosby's medical dictionary defines transient as "pertaining to a condition that is temporary." Using the word transient to describe the human body's foreign body response to the TVT mesh implies the response dissipates with time. In my experience, this does not accurately describe the human body's foreign body response to transvaginal placed mesh.

In my experience when dealing with synthetic mesh-induced foreign body response, the degree of inflammation and scarring around the mesh is intense and chronic. More often than not, when removing exposed mesh, I am unable to completely remove the entire mesh implant because of the intensity of inflammation and extensive scarring induced by mesh incorporation into the host tissues. Moreover, in all of my experiences removing mesh, residual scarring of the vagina and peri-vaginal tissues persists and is even more severe in the instances where residual pelvic mesh is left in the patient.

The TVT IFU does not mention: mesh contraction; dyspareunia; mesh shrinkage; scar plate formation; or the difficulty in removing mesh in the event of an adverse event. These events are all part of my informed consent conversation today. I have treated patients implanted with mid-urethral slings, including the TVT for these conditions. These events were reported in the mid-urethral sling literature prior to when Ms. Phillips was implanted. In my opinion, a patient considering a mid-urethral sling cannot be properly consented without discussing these potential adverse events.

General Opinion No. 2

Safer alternatives designs and procedures existed in 2005 that have a lesser risk of erosion and dyspareunia with substantially equivalent efficacy.
In 2005, alternative successful and safer sling procedures were available, including autologous fascial slings using rectus fascia sutured to the bladder neck and tied to itself over the rectus fascia. Ms. Phillips was unable to receive proper informed consent relating to this safer alternative because of the lack of information in the

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TVT IFU inherent to the risks of using synthetic mesh. As such, Dr. Kim was unable to warn Ms. Phillips of the subsequent complications she has suffered from.

Case Specific Opinion No. 1

Ms. Phillips suffered scar plate formation as a result of the physical properties of the TVT device. These conditions are documented in my independent medical evaluation (IME) of Ms. Phillips.

During my physical examination Ms. Phillips, I identified vaginal scarring along the anterior vaginal wall in the area of her TVT sling which was palpable underneath this tissue and painful to palpation.

I have observed scar plate formation in patients such as Ms. Phillips who have had TVT slings implanted.

Case Specific Opinion No. 2

Ms. Phillips' pelvic pain and dyspareunia was in part caused by scar plate formation around the TVT device. Recognized causes of dyspareunia following synthetic sling surgery include: (1) erosion/extrusion; (2) mesh contraction; (3) paraurethral banding; (4) scarring with reduced elasticity; (5) infection and inflammation including but not limited to vestibulitis; (6) neuromuscular injury (7) lichen sclerosis; (8) vaginal tissue atrophy; and (9) pelvic floor dysfunction.

I am able to rule out erosion as a cause of Ms. Phillips' dyspareunia after 2005. There is no evidence of this in the medical records I've reviewed nor in my pelvic examination performed during my IME.

I am able to rule in scarring with reduced elasticity as a cause of Ms. Phillips' vaginal pain and dyspareunia. I identified this finding during my physical examination of Ms. Phillips. Specifically, her sling was palpable in an area of tender and scarred anterior vaginal wall tissue. This finding enables me to rule in contraction and scarring as a potential cause of Ms. Phillips' dyspareunia.

I am able to exclude paraurethral banding as a cause of Ms. Phillips' dyspareunia and vaginal pain because I have seen no paraurethral banding documented.

I am able to exclude vestibulitis a cause of Ms. Phillips' vaginal pain and dyspareunia. I am able to include lichen sclerosis and vulvovaginitis as possible

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causes of Ms. Phillips' vaginal pain and dyspareunia. During my IME, I encountered findings consistent with both of these disease states along her posterior vulvar area and posterior vaginal wall at the introitus. It is unclear, however, whether she had these problems between 2006 and 2009 when she was last sexually active with her husband who died around 2009.

Vaginal tissue atrophy is not completely excludable as a cause of Ms. Phillips' dyspareunia. Although she never was diagnosed with this condition between 2006 and 2009 when she was last sexually active with her husband, she had no evidence of any pelvic exams. In fact, her last known pelvic exam before mine in June of 2016 was back in 2005 before her sling surgery (at which time there was no evidence of vulvovaginal atrophy). She was prescribed Premarin in 2009, when she was 56 years of age, but the reasons for prescribing this medication are unclear. Therefore, although unlikely to be a significant contributing cause of her vaginal pain and dyspareunia, it is not totally excludable as such.

I am able to exclude pelvic floor dysfunction as the cause of Ms. Phillips' dyspareunia. The absence of documented tenderness to the pelvic floor musculature during my IME allows me to exclude pelvic floor dysfunction as a potential cause of Ms. Phillips' dyspareunia.

Case Specific Opinion No. 3

Ms. Phillips continues to have dyspareunia and pelvic pain presently. As part of my expert review and preparation of my opinion regarding Ms. Phillips, I performed an independent medical exam of this patient on June 17th, 2016. At that time, the patient reported several bothersome symptoms including voiding dysfunction, pelvic pain and dyspareunia. Her voiding dysfunction consisted of MUI, with both significant SUI and UUI symptoms, worse than before her sling surgery, such that she has to use pads on occasion for protection (whereas before 2005 she did not require pads). She also complained of intermittent dull vaginal and pelvic pain with a pressure sensation that worsened with walking. She described having had some minimal dyspareunia before her sling surgery but having such severe pain with intimacy that she had only attempted sex once with her husband and had to stop because of intense pain. She described that experience as a "rough, tearing sensation" with severe pain, most notably at the vaginal introitus.

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On physical exam, there was mild vulvar atrophy noted, as well as an inflamed and tender posterior vaginal wall with some whitish vulvar plaque, also quite sensitive to exam. Her sling was seated in the proper location, along the anterior vaginal wall in the area of the mid-urethra. Scarring and tenderness was appreciated along the area of the sling which was palpable form the left vaginal sulcus through to the right vaginal sulcus. As part of the foreign body reaction to synthetic mesh the periurethral, perivesical, and vaginal tissues create dense fibrotic scar tissue which compromises the elasticity and compliance of these tissues. As such, when patients present with voiding dysfunction following synthetic mesh sling implantation, it tends to manifest itself as both obstructive in nature in combination with mixed urinary incontinence (MUI). This relates to a combination of factors, one being the development of non-compliant "pipestem" urethral tissues that are unable to coapt and therefore hold urine; the second factor relates to a combination of (1) inflammation rendering the bladder muscle (or detrusor muscle) unstable, as well as (2) scarring of the bladder muscle adjacent to the synthetic mesh foreign body response, in which the bladder muscle's ability to contract is compromised because of scarring and fibrosis. Ms. Phillips currently has this complaint having evolved from a patient with a mild to moderate SUI- dominant incontinence picture to a severe form of MUI, with relatively equal amounts of SUI and UUI.

Case Specific Opinion No. 4

Ms. Phillips' future prognosis as it relates to her vaginal pain, dyspareunia, and voiding dysfunction is guarded. Because she has pelvic mesh still inside of her body, she will continue to suffer from vaginal pain and dyspareunia. Moreover, she has pelvic tenderness and residual scar tissue in the area where her mesh is located. Even if she were to have all of her mesh removed, the surgery require to execute this procedure is challenging, complicated, and likely to create further vaginal scarring. I anticipate that if heroic surgery were performed to remove all of her mesh that she would develop further scarring and fibrosis inherent to this procedure. Although these interventions could be somewhat helpful, they most certainly will not resolve the voiding dysfunction she currently suffers from.

With regards to her dyspareunia, her symptoms might be partially ameliorated with sling removal. Once again, this would be a heroic procedure likely performed in a tertiary academic center and would likely create further fibrosis and scarring which would more likely than not result in persistent dyspareunia. In

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summary, within a reasonable degree of medical certainty, the voiding dysfunction, vaginal pain, and dyspareunia will be a lifelong condition for this patient.

I reserve the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 8th day of July, 2016

Sincerely,

Konstantin Walmsley, M.D.